

**Conclusions:** The presence of false lumen thrombus is associated with an increase in long-term aorta related morbidity and mortality. These findings may have implications on risk stratification, frequency of surveillance imaging, and future treatments.

#### TCT-543

##### Covered Endovascular Reconstruction of Aortic Bifurcation or CERAB-technique for treating extensive aortoiliac occlusive disease.

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**Background:** We developed the Covered Endovascular Reconstruction of Aortic Bifurcation or CERAB-technique for extensive and/or recurrent aortoiliac occlusive disease using V12 covered balloon expandable stents (Atrium Maquet Getinge Europe BV) to rebuild the aortic bifurcation.

**Methods:** Endovascular bifemoral recanalisation of the aortoiliac axes; placement and expansion of a 12 mm V12 Large Diameter in the distal aorta (9 Fr). Pick up of the already expanded V12 stent with an large balloon (adapted to the aortic diameter). The balloon is so positioned that the distal marker is about 15 mm proximal to the distal stent margin. After positioning and expansion, the distal stent part becomes funnel-shaped. Two iliac covered stent-grafts are then placed in this segment, in a "kissing-stent" configuration and inflated. Both stents are now making a very tight combination with the aortic stent, as were they moulded together, simulating a new bifurcation

**Results:** Two-centre prospective, non-randomised, follow-up study. We treated now 70 patients with acute, chronic or recurrent aortoiliac occlusive disease. Technical success rate up till now was almost 95%. Follow-up 52 – 1 months. 5 patients died of non-interventional causes. Five patients re-occluded, mainly due to progressive distal peripheral disease. They received successfully thrombolysis and treatment of the outflow problems. The other patients showed no complications.

**Conclusions:** Covered Endovascular Reconstruction of Aortic Bifurcation or CERAB is safe and feasible and can be performed completely percutaneous. A larger population, longer follow-up, further haemodynamic investigation is needed Distal peripheral outflow needs to be sufficient enough. It can be combined as a "hybrid" procedure. CERAB can be used for the treatment of recurrent or in-stent disease It is even feasible to treat lesion that extend to the iuxta and/or supral renal aortic region

#### TCT-544

##### The Potential Role of Statin in Patients with Critical Limb Ischemia.

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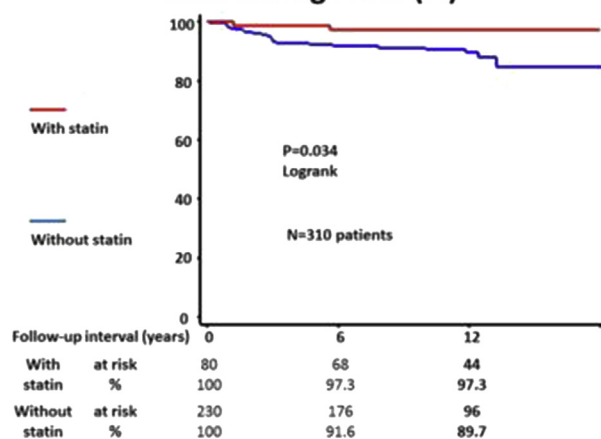
**Background:** Revascularization is the optimal treatment to avoid major amputation for critical limb ischemia (CLI) patients. Although previous studies report that statin administration is associated with a reduced risk for cardiovascular events, the efficacy for CLI patients is unclear. In this study, we aimed to compare the outcomes in CLI patients with statin administration and without statin administration after endovascular therapy (EVT).

**Methods:** This study is a subanalysis from Endovascular Treatment for Infra-inguinal Vessel, in patients with critical limb ischemia, - A Prospective, Multi-center, 12 month follow-up Registry in Japan: Olive Registry. From November 2009 to December 2011, a total of 310 patients with CLI who underwent EVT for infrainguinal artery disease were enrolled. The outcome measures were limb salvage and major adverse limb event (MALE). MALE was defined as major amputation or major reintervention including surgical procedure.

**Results:** The mean follow-up period was 294 ± 138 days. Sixty-five percent were male, 26% had statin administration. Rutherford class IV was found in 38 patients, V in 217 patients and VI in 55 patients. Kaplan-Meier survival curve showed that the limb salvage rate at one year was 97.3% in the statin group, 89.7% in the without statin group (P=0.03). In adjusted model, limb salvage rate and freedom from MALE were statistically higher in the statin group (P<0.01).

**Conclusions:** Statin administration after infrainguinal angioplasty for CLI patients improved limb salvage rate and freedom from MALE.

#### Limb salvage rate (%)



#### TCT-545

##### The AURORAA registry : 1 year results using interwoven nitinol stents for extensive distal femoropopliteal occlusive disease.

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**Background:** In the endovascular treatment of extensive disease in the distal superficial femoral and popliteal level, you can encounter flow limiting problems, where stent placement is needed after balloon angioplasty. At the moment most of the standard bare nitinol stents will have difficulties in these areas. With the introduction of the Supera stent (IDEV Technologies, Inc., Texas, US) we may have an answer in treating those problematic lesions

**Methods:** Because of the Supera new design; with 6 interwoven nitinol wires, it has extraordinary characteristics : very flexible, kink, fracture and crush resistant together with great radial force. We have treated more than 100 patients with extensive distal femoropopliteal disease (TASC II C & D) with heavy calcifications, occlusions, recurrent disease, stent fractures etc. These lesions, that not responded to balloon angioplasty and that needed stent placement, were all treated with placement of Supera stents.

**Results:** Results of the single centre prospective AURORAA registry : Follow up done by ultrasound. Five patients died of non-interventional causes. Six months primary patency was more than 90%. Twelve months primary patency was around 81%. We observed further more no stent fractures or flow limiting kinking in this very difficult "to stent" area (distal superficial femoral artery & popliteal artery). Average lesion length: 14 cm; average stent length : 18 cm. Technical success rate :96 %

**Conclusions:** The Supera stent can be a solution when the use of a "classic" nitinol stent is not indicated or favourable, especially in the femoropopliteal area. It has very good patency rates, despite the very difficult region to treat This self expandable stent system can be a necessary complement in your tool box due to its special characteristics

#### TCT-546

##### Safety and feasibility of one day discharge after endovascular revascularization of lower extremities in elderly.

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**Background:** The elderly have a high prevalence of peripheral arterial disease (PAD) and it seems that they may be less suitable for a one day discharge after endovascular revascularization (ER) mainly due to a higher ratio in hemorrhage complications. Therefore we sought to evaluate whether the advantages of one day discharge after ER on lower extremities can be safely extended for the elderly.

**Methods:** Between January 2008 and June 2012, 455 ER were performed on lower extremities with Bivalirudin as an anticoagulant. The decision of deployment the vascular closure device (VCD) was left to the operator discretion. Patients 70 years old and older were included to the study group (n=235). The rest of the patients created the control group (n=220). The follow up was done at 24 hours and 30 days after

discharge. Retroperitoneal bleeding, pseudoaneurysm, arteriovenous fistula and hematoma were considered the composite endpoint of major vascular complications (MVC). Secondary endpoints were: death, stroke, myocardial infarction, amputation and target lesion revascularization (TLR).

**Results:** The study cohort had average age of 79 (range 70–95) years compared to 60.9 in the control group (range 38–69). Study group were more likely to be female, but less likely to be current smokers, diabetic and dialysis reliant ( $p < 0.001$ ). There were no differences between groups in VCD deployment and critical limb ischemia. The mean time to ambulation in the elderly and control group were 3.6 hours ( $\pm 1.2$ ) and 3.4 hours ( $\pm 1.3$ ) respectively ( $p = 0.8$ ). In 24 hours as well as in 30 days follow up there were no significant differences in the primary and secondary endpoints between groups. Current smoking status (OR=2.35, 95% CI: 0.485–11.46) in the octogenarians, whereas female sex (OR=1.75, 95% CI: 0.389–7.86) and hypercholesterolemia (OR=6.739, 95% CI: 0.294–154.4) in controls were found to be independent predictors of MVC at 30 days.

**Conclusions:** The same day discharge after ER on lower extremities is safe and feasible in the elderly.

#### TCT-547

##### Long term outcomes of percutaneous lower- extremity arterial interventions with balloon angioplasty versus atherectomy- propensity score matched registry.

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**Background:** The atherosclerosis plaques have different morphology from soft neointimal plaques to hard calcified lesions. Therefore, we sought to evaluate the efficacy of percutaneous balloon angioplasty (PTA) versus atherectomy (AT) endovascular revascularization which type was attuned by operator.

**Methods:** Between 2008 and 2013 a total of 419 endovascular revascularizations were performed on arteries of lower extremities. In this registry we include patients with claudication as well as with critical limb ischemia (CLI). The endpoints were considered as target lesion revascularization (TLR), amputation, major adverse cardiovascular event (MACE) and bailout stenting (BS). MACE was defined as death, myocardial infarction and stroke. The type of atherectomy (excisional- soft plaque, orbital- calcified plaque, with active aspiration- with a thrombus) was left to the operator's discretion.

**Results:** The PTA was performed on 215 patients, whereas AT was used in 204 cases (Silver Hawk TM, EV3- MN, USA -125; CSI360° MN, USA- 66 Pathway Medical Technologies- 13). The mean follow up time was 500 ( $\pm 454$ ) days. There were no significant differences in baseline characteristics between groups with the exception of increased coronary artery disease, dialysis and CLI for PTA group. There were significant differences in TVR (PTA: 32% vs. AT: 21%;  $p=0.01$ ), death (PTA 8% vs. AT: 2%;  $p=0.009$ ) and BS (PTA: 9% vs. AT: 1%  $p<0.001$ ). Kaplan- Mayer analysis showed no significant differences between groups in time to TLR, amputation, death. After adjustment this was sustained.

**Conclusions:** In this observational analysis, atherectomy endovascular revascularization offered better long term outcomes than balloon angioplasty.

#### TCT-548

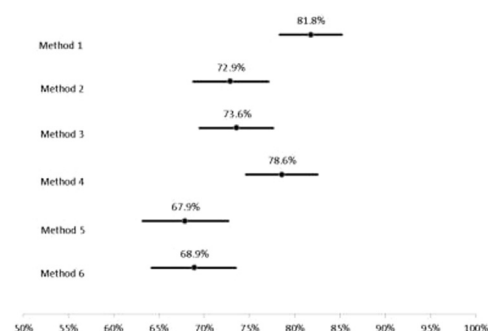
##### Variability in Analysis of Freedom from Primary Patency from Trials Assessing Stent Implantation in the Superficial Femoral Artery.

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**Background:** Primary Patency (PP) in trials assessing Superficial Femoral Artery (SFA) stenting is defined as a combination of vessel patency assessed by Duplex ultrasound (DUS) at 12 month visit and freedom from revascularization of the index vessel through 12 month follow-up. Patients are thus more likely to lose PP during the mandated DUS assessment. Moreover, DUS is performed within a pre-specified window which exceeds 12 months, thus the time frame for analyzing patency via DUS exceeds the time frame by which revascularization is captured. There are no guidelines as to the correct method for presenting these analysis in reports from clinical trials. We aimed to analyze the implications of applying different methods in assessing freedom from loss of PP in studies assessing stenting for SFA disease.

**Methods:** We simulated a dataset of patients and outcomes based on existing available results from SFA stenting trials. Six different approaches to Kaplan Meier (KM) analyses were applied based on entry criteria into and time frame of the KM model.

**Results:** Six KM estimates of freedom from loss of PP were generated for each of the 10,000 simulation sets. The six different methods averaged from 67.9% to 81.8%.



**Conclusions:** Survival analyses of freedom from loss of PP vary substantially according to the methods employed. These may lead to misrepresentation of results from clinical trials. The development of a unified approach is advocated.

#### TCT-549

##### Sub-analysis of the CONFIRM Registries: Outcomes in Claudicant Patients Treated for Peripheral Arterial Disease with Orbital Atherectomy

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**Background:** Intermittent claudication affects 2.5% of women and 5% of men over the age of 60. Advanced age, diabetes, and renal insufficiency predispose patients to intra-arterial calcium which is a predictor of poor endovascular treatment success. Methods of treating peripheral arterial disease (PAD) have evolved and now include minimally-invasive endovascular procedures, utilizing orbital atherectomy (OA) which can modify calcific plaque both above and below-the-knee.

**Methods:** Three consecutive CONFIRM patient registries were conducted prospectively and enrolled patients on an "all comers" basis to evaluate the use of orbital atherectomy in peripheral lesions of the lower extremities. Analysis of all 3135 patients enrolled in the CONFIRM I-III registries revealed 1698 patients with claudication (Rutherford Class 1-3) and documented lesion morphology. We analyzed the CONFIRM series to compare procedural complications after OA treatment of lesions with moderate/severe calcium versus lesions without moderate/severe calcium in claudicant patients.

**Results:** Eighty-two percent of claudicants treated with OA had moderate/severely calcified lesions. There was no significant difference in the percentage of perforations (0.6% vs 0%), slow flow (2.9% vs 2.6%), closure (1.4% vs 2.3%), spasm (3.8% vs 6.3%), embolism (1.7% vs 2.6%), or thrombus (1.1% vs 1.3%), in claudicants with moderate/severely calcified lesions vs without moderate/severely calcified lesions, respectively. Claudicants with moderate/severe calcium had fewer dissections than those without moderate/severely calcified lesions (10.9% vs 16.2%,  $p=0.004$ ).

**Conclusions:** The majority of the claudicant patients in this study had lesions with moderate to severe calcification, yet the occurrence of adverse events was low after treatment with orbital atherectomy. Orbital atherectomy is a safe tool for restoring blood flow in the lower extremities of claudicant patients regardless of arterial calcium burden.

#### TCT-550

##### Assessment of Stability and Bactericidal Activity of a Novel Triple Antimicrobial-Bonded Graft for Preventing Perioperative Aortic Infection

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**Background:** Prosthetic aortic grafts remain problematic despite enhancements in biomaterials and production prosthetics, improved surgical techniques, and a better understanding of the pathogenesis of graft infections. Previously, we investigated a locally developed technique of bonding aortic grafts with 3 antimicrobials to prevent early (within 2 weeks) direct perioperative bacterial contamination related to aortic graft operations. In the current phase, we attempted to determine whether the concentrations of the antimicrobials bonded to the graft are sufficient to prevent postoperative aortic graft infections for a longer period (8 weeks).

**Methods:** Nine Sinclair miniature pigs received a 6-mm vascular Dacron graft in the infrarenal portion of the abdominal aorta. Six pigs received grafts chemically bonded with 60-mg/mL solutions of rifampin, minocycline, and chlorhexidine; 3 pigs received unbonded grafts. Before implantation, the 6 bonded grafts and 2 of the unbonded grafts were immersed for 15 minutes in a 2-mL bacterial solution containing 1 to  $2 \times 10^7$  colony-forming units (CFUs)/mL of *Staphylococcus aureus* (ATCC 29213); the 3rd unbonded graft served as a control. The pigs were observed for 8 weeks after graft implantation; then the pigs were sacrificed, and the grafts were excised. Before